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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/582,734
Filing Date: October 06, 2000
Appellant(s): MENDEL-HARTVIG ET AL.

Holly D. Kozlowski
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 1, 2004.

(1) ***Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

(2) ***Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of the claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of the Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of the Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: the rejection of claims 1-4 and 6-17 under 35 U.S.C. 112 second paragraph regarding the recitation "adapted" is withdrawn.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 1-4 and 6-35 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192 (c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

4,981,786	DAFFORN et al	01-1991
WO 95/16914	ROBINSON et al	06-1995

4,446,231	SELF et al	05-1984
5,556,789	GOERLACH-GRAW et al	09-1996

(10) Grounds of Rejection

Upon further consideration, the 112 second paragraph rejection of claims 1-4 and 6-17 is withdrawn.

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claims 1, 3, 7, 9, 10, 13, 14, 18, 20, 21, 24, 25, 27, 28 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Dafforn et al (US 4,981,786).

Dafforn et al disclose an immunoassay device and method for determining an analyte in a sample. Dafforn et al also disclose that the device comprises a bibulous material which is susceptible to traversal by an aqueous medium in response to capillary force (flow matrix), (col 7, lines 8-10). Dafforn et al disclose that the device may be used in assays wherein absorbent material is utilized to assist the flow of liquid away from a contact portion where the absorbent material is contacted with a medium containing the analyte to be determined or reagents for analyzing for the analyte (col 4, lines 10-16). Dafforn et al disclose the device comprises a first means for introducing a sample into the device and second means other than the first means for introducing a liquid reagent other than the sample into the device (col 3, lines1-20). Dafforn et al

disclose that the liquid reagent can be an ancillary reagent such as a buffer or a labeled reagent (Reactant*). Dafforn et al disclose that the labeled reagent can be provided as liquid reagent or predeposited (col 19, line 15 – col 20, line 22). Dafforn et al disclose that the liquid reagent can be added upstream of the test solution (sample) (col 18, lines 27-29). Dafforn et al also disclose that both of these application zones are located upstream of an immunosorbing zone (detection zone) and that specific binding members (antibodies) (Reactant I) are immobilized in the immunosorbing zone (col 18, line 3 – col 19, line 48). Dafforn et al disclose that the strip may be coated with a material (col 19, lines 1-9). Dafforn et al disclose that the device contains dividers (spacers) between the first means and second means. Dafforn et al also disclose that the sample may be introduced before the liquid reagent if so desired (col 18, lines 20-32). Dafforn et al disclose that the contact portion can also serve as the immunosorbing zone (detection zone) or separate immunosorbing zones can be utilized depending on the particular assay protocol chosen (col 18, lines 45-48). Dafforn et al also disclose that the application of liquid can be performed simultaneously in the application zones (col 24, lines 30-32). Dafforn et al also disclose that the reagents can be predeposited in the matrix. Dafforn et al also disclose packaging the components into a kit.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 4, 6, 8, 11, 19, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dafforn et al (US 4,981,786).

See above for teachings of Dafforn et al.

Dafforn et al differ from the instant invention in failing to specifically teach n">n' wherein Reactant*, is upstream of a liquid application zone for sample and the liquids are applied substantially simultaneously to the flow matrix.

Dafforn et al is silent with respect to substantially simultaneously adding Reactant*, upstream of liquid application zone for sample. However, Dafforn et al specifically teach that the Reactant* can be applied upstream of the liquid application zone for sample. Dafforn et al also disclose many embodiments regarding Reactant* in which Reactant* is applied upstream of the application zone of sample or to the same zone as the sample. Although, Dafforn teaches that when (Reactant*) is added upstream of sample, that the liquid reagent usually is added following the addition of sample (col 13, lines 32-44), Dafforn also teaches the addition of liquid reagents simultaneously (col 24). Therefore, it would have been obvious to one of ordinary skill in the art to add Reactant* upstream of a liquid application zone for sample and to apply

the liquids simultaneously in order to optimize assay conditions. Further, it is well settled that a reference must be evaluated for all disclosures not just its preferred embodiments. *In re Mills,* 470 F. 2d 649, 176 USPQ 196 (CCPA 1972).

Claims 12, 15, 16, 26, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dafforn et al in view of Robinson et al (WO 95/16914).

See above for teachings of Dafforn et al.

Dafforn et al differ from the instant invention in failing to specifically teach n">n' wherein Reactant*, is upstream of a liquid application zone for sample and the liquids are applied substantially simultaneously to the flow matrix.

Robinson et al disclose the use of calibration zone(s), in which a calibration reagent is immobilized and has biospecific affinity for the analyte of interest or the binding partner of interest (page 15, lines 15-24). Robinson et al also disclose a releasable reagent predeposited (abstract). Robinson et al also disclose that the device may be a flow through device such as test strip (page 5, lines 7-22). Robinson et al also disclose that the specific binding partner can be coupled to or conjugated to the calibrator (see page 17), to form a complex for detection. Robinson et al disclose that the reagents may be antigen/antibody complexes. Robinson et al disclose that calibrator zones used in this manner offers means for calibrating the assay as part of the assay procedure (page 3, lines 15-16) and also provides advantages for additional compensation for various factors in the assay system which may influence the level of signal observed (page 14, lines 24-26).

It would have been obvious to one of ordinary skill in the art to incorporate the use of a calibrator zone as taught by Robinson et al into the method and device of Dafforn et al because Robinson et al disclose that calibrator zones used in this manner offers means for calibrating the assay as part of the assay procedure (page 3, lines 15-16) and also provides advantages for additional compensation for various factors in the assay system which may influence the level of signal observed.

Claims 17 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dafforn et al in view of Self et al (US 4,446,231).

See above for teachings of Dafforn et al.

Self et al disclose that immunoassays are used for the detection and/or determination of autoimmune diseases. Self et al shows that immunoassays have a wide application, in both clinical and non-clinical fields and that they are particularly useful in any circumstance where it is necessary to detect and/or determine small or very small amounts of substances.

It would have been obvious to one of ordinary skill in the art to use immunoassays as taught by Self et al for the diagnosis of autoimmune diseases because Self et al shows that immunoassays are used for the detection and/or determination of autoimmune diseases and that immunoassays have a wide application, in both clinical and non-clinical fields and that they are particularly useful in any circumstance where it is necessary to detect and/or determine small or very small amounts of substances. Therefore it would have been obvious to one of ordinary skill in

the art to use the device and method of Dafforn et al for diagnosing autoimmune disease.

Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dafforn et al in view of Goerlach-Graw et al (US 5,556,789).

See above for teachings of Dafforn et al.

Dafforn et al differ from the instant invention in failing to specifically teach wherein each spacer comprises a strip attached to the flow matrix.

Goerlach-Graw et al disclose barriers in the form of strips in a flow matrix. Goerlach-Graw et al disclose that such barriers can be integrated at any desired position between the sample application zone and the reagent zone (col 6). Goerlach-Graw et al disclose that these barriers provide for a device wherein flooding of the test elements with sample liquid is avoided by using these retardation zones.

It would have been obvious to one of ordinary skill in the art to incorporate barriers such as taught by Goerlach-Graw et al into the device and method of Dafforn et al because Goerlach-Graw et al shows that these barriers provide for a device wherein flooding of the test elements with sample liquid is avoided by using these retardation zones.

(11) Response to Arguments

Appellant argues that the claimed methods and devices are not anticipated by Dafforn et al.

Appellant argues that Dafforn et al fails to teach or suggest a method or device wherein flow is initiated by adding liquid to each zone in such a way that liquid$_{n+1}$

contacts the flow matrix substantially simultaneously with and is transported through the matrix immediately after liquid$_n$, added to the nearest downstream application zone LZ_n. Appellant states that the only specific mention of simultaneous application which Appellants find in the teachings of Dafforn et al is at column 24, beginning at line 22 wherein an assay is conducted by adding a sample suspected of containing HCG at the first opening and simultaneously adding a developer solution containing enzyme substrate at the second opening. During subsequent incubation, HCG binds to the conjugate, the complex is carried by the moving developer to the detection zone where it binds, and the bound complex acts on the substrate to produce color at the detection zone where it binds, and the bound complex acts on the substrate to produce color at the detection zone when HCG is present in the sample. Appellants state that Dafforn et al provide no teaching or suggestion relating to simultaneous contact and sequential flow of reagents through the matrix. This is not found persuasive because it appears that Applicant is trying to assert that two separate liquid fronts are moving toward the detection zone, one containing analyte (i.e. sample), and the other containing the labeled reagent. And that a complex between the analyte and the labeled reagent is not formed prior to both liquid-fronts reaching the detection zone. If this is a correct interpretation of the argument, it is not found persuasive because it is not on point. The claims are not limited to a method where the labeled reagent is moving in a separate front, i.e. behind a sample liquid. Instead, the claims recite an embodiment where the labeled reactant is located in the same zone where sample is added, (i.e. $LZ_{n"}R^*$ and LZ_n with $n" \geq n'$), since n is recited as the position of the application zone (LZ_n), the

indication that n" is $\geq$ n' is interpreted as an embodiment where the sample application zone and the zone for the labeled reactant is the same, i.e. Dafforn, column 24, lines 23-46. In this case, a complex between the analyte and the labeled reactant is formed when sample is added to LZ_n, and this complex is moving in front of any liquid that is added to the other liquid addition zones. Because the claims do not make clear what "liquid" may be added to the various zones, this "liquid" could be buffer or substrate solution, in which case, after the complex of Dafforn reaches the detection zone, the bound complex acts on any substrate solution that subsequently enters the detection zone, resulting in a color change. These teachings are seen to be the same as those of the instant claims.

Appellant further argues that the complex and the developer mix with one another and relies upon the statement in Dafforn that the complex is carried by the moving developer to the detection zone (column 24, lines 33-34). This is not found persuasive because of reasons stated above. Further, it is noted that the instantly recited claims do not exclude any mixing or carrying. The instantly recited claims only requires that flow is initiated by adding liquid to each zone in such a way that $liquid_{n+1}$, added to the application zone LZ_{n+1}, contacts the flow matrix substantially simultaneously with and is transported through the matrix immediately after $liquid_n$ added to the nearest downstream application zone LZ_n. There is no recitation excluding any mixing or carrying or that all reagents and sample reach the detection zone in the exact same order without any mixing or carrying. Further, as stated above Dafforn teaches that the labeled reagent (enzyme conjugate) and sample are provided in the same application

area and that developer (liquid reagent, substrate) is provided in an application area upstream of the sample and labeled reagent (enzyme conjugate). The labeled reagent (enzyme conjugate) and analyte in the sample bind to form a complex and the complex is captured in the detection zone and the complex and substrate react within the detection to produce color at the detection zone. If the developer (substrate) and complex mixed prior to the detection zone a color would appear prior to the detection zone which would be contrary to the teachings of Dafforn et al.

Appellant further argues the result in sequential transport is contrary to the teachings of Dafforn et al at column 24 and that one of ordinary skill in the art will recognize that, as discussed in the present specification, a liquid added in an application zone may have a tendency to spread on top of the matrix to parts of the matrix outside the zone and that Dafforn et al have mixing as their objective as the developer carriers the complex to the detection zone. This is not found persuasive because of reasons of record and further it is noted that the instantly recited claims do not exclude mixing. Also it is noted with respect to claims 1 and 18 as instantly recited. It appears that the claims are missing an essential element for achieving sequential flow without mixing of fluids between the two application zones. On page 6, lines 10-18 of the specification the applicant discloses that "A liquid added in an application zone may have a tendency to spread on top of the matrix to parts of the matrix being outside the zone. For adjacent zones this means that liquids may be mixed with each other in an undesired way. To avoid this, physical barriers delimiting two adjacent application zones (zone spacers) are placed. The barriers should primarily be placed on top of the

matrix, but may be extended down into the matrix without completely quenching the flow. Therefore, if appellant maintains that Dafforn et al involves mixing, it is the Examiner's position that since independent claims 1 and 18 do not recite spacers, that applicant's invention would also have mixing occurring. The first recitation of spacers does not occur until claim 10 (see above rejection). Further, as stated above Dafforn teaches spacers as recited in claim 10.

Appellant argues that claims 3 and 20 are independently patentable. Appellant argues that Dafforn et al fails to teach an analytically detectable Reactant* application zone and a sample application zone that coincide and particularly with at least one addition liquid application zone. This is not found persuasive because Dafforn et al clearly teach an application zone wherein labeled reagent (enzyme conjugate) and sample are provided in the same application area and that developer (liquid reagent, substrate) is provided in an application area upstream of the sample and labeled reagent (enzyme conjugate). Therefore, Dafforn teaches an application zone for both labeled reagent and sample and a separate application zone for developer (liquid reagent).

Appellant argues that claim 7 is independently patentable. Appellant argues that Dafforn et al fail to teach a method according to claim 7 wherein application of liquid is performed simultaneously in all liquid application zone and each liquid contacts the flow matrix substantially with and is transported through the matrix immediately after liquid added to the nearest downstream application zone. This is not found persuasive because of reasons stated above.

Appellant argues that claims 10 and 24 are independently patentable. Appellant argues that the dividers (spacers) taught by Dafforn et al are the housing portions between sample application wells and Appellants find no dividers provided on a flow matrix in Dafforn et al. This is not found persuasive because instantly recited claims 10 and 24 merely recite wherein the zones $LZ_m..LZ_n..LZ_1$ have zone spacers between each other. One skilled in the art would recognize that the dividers of Dafforn et al are incorporated as part of the flow matrix between the application zones and thus would act as spacers. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that thee features upon which applicant relies (i.e., in the flow matrix, rather than in a housing well) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns,* 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, Dafforn reads on the instantly recited claims.

Appellant argues that claim 21 is independently patentable. Appellant argues that Dafforn et al fails to teach or suggest a device wherein an analytically detectable reactant is predeposited in the device and is adapted for sequential flow to a detection zone. This is not found persuasive because of reasons stated above and further because Dafforn et al clearly discloses a device wherein the analytically detectable reactant is predeposited (see column 24). Dafforn teaches that an enzyme conjugate has been predeposited in the device (see column 24).

Appellant argues that claims 2 and 19 are nonobvious over Dafforn et al. Appellant argues that Examiner fails to indicate why one of ordinary skill in the art would be motivated to modify either the method or the device taught by Dafforn et al to arrive at the method and device defined by claims 2 and 19 and that the modification would prevent the developer solution of Dafforn et al from mixing with the sample-enzyme conjugate complex. This is not found persuasive because as stated in the previous office action and advisory action Dafforn et al specifically teach that the Reactant* can be applied upstream of the liquid application zone for sample. Dafforn et al also disclose many embodiments regarding Reactant* in which Reactant* is applied upstream of the application zone of sample or to the same zone as the sample. Although, Dafforn et al teaches that when (Reactant*) is added upstream of sample, that the liquid reagent usually is added following the addition of sample (col 13, lines 32-44), Dafforn also teaches the addition of liquid reagents simultaneously (col 24). Therefore, it would have been obvious to one or ordinary skill in the art to add Reactant* upstream of liquid application zone for sample and to apply the liquids simultaneously in order to optimize assay conditions. Further, it is well settled that a reference must be evaluated for all disclosures no just its preferred embodiments. *In re Mills, 470 F. 2d 649, 176 USPQ 196 (CCPA 1972).* Also, regarding appellants' argument that the modification would prevent the developer solution of Dafforn et al from mixing with the sample-enzyme conjugate complex. This is not found persuasive because as stated above the instantly recited claims do not exclude mixing and further as stated above Dafforn does not teach mixing. Also one skilled in the art would recognize that when

the enzyme conjugate (labeled reagent) was added upstream of the sample, the developer solution would be applied to an application area located above both enzyme conjugate area and the sample area because Dafforn specifically teaches embodiments in which the developer is applied at the furthest upstream application area (figures 6-9 and column 19, lines 49-57).

Appellant argues that claim 4 is nonobvious over Dafforn et al. Appellant argues that Dafforn fail to teach a method wherein analytically detectable reactant is predeposited in a liquid application zone and is sequentially transported to a detection zone. This is not found persuasive because of reasons stated above and further because Dafforn et al clearly discloses a method wherein the analytically detectable reactant (enzyme conjugate) is predeposited (see column 24). Dafforn teaches that an enzyme conjugate has been predeposited in the device (see column 24).

Appellant argues that claims 6 and 22 are nonobvious over Dafforn et al. Appellant argues that Dafforn et al fails to teach whether or not the liquid application zones are immediately adjacent to one another. This is not found persuasive because Dafforn et al teaches multiple application zones, which are adjacent to each other (see figures 1-9).

Appellant argues that claims 8 and 23 are nonobvious over Dafforn et al. Appellant argues that the only teaching Appellants find by Dafforn et al relating to simultaneous application of liquids is the example described in column 24. Appellants argue that Dafforn et al fails to teach a plurality of liquid application zones as required by claims 8 and 23 and fails to teach the motivation to modify the methods and devices

of Dafforn et al. This is not found persuasive because as stated above Dafforn et al teaches many different embodiments using a plurality of application areas (col 19 and figures 6-9) and Dafforn et al also teaches simultaneous application of sample and reagents and one of ordinary skill would be motivated to optimize assay conditions when using a plurality of application areas.

Appellant argues that claim 11 is nonobvious over Dafforn et al. Appellant argues that Dafforn fails to teach or suggest a method wherein different liquids applied at the respective openings are sequentially transported to the detection zone and that Dafforn teaches that such liquids mix. This is not found persuasive because the instantly recited claims do not exclude mixing and further as stated above, it is the Examiner position that Dafforn does not teach mixing (see above for reasons).

Appellant argues that claims 12, 15, 16, 26, 29 and 30 are nonobvious over Dafforn et al and Robinson et al. Appellant argues that Dafforn et al fail to teach or suggest an additional zone $LZ_{n''}R$ as presently required by claims 12 and 26, or relating to calibration, particularly, integral with their device, or relating to a calibration zone in their device, calibrator predeposited in or applied to a matrix, or a binder for a calibrator in a calibration zone, as required by claims 15, 16, 29 or 30. This is not found persuasive because Dafforn et al specifically teaches that additional application zones can be implemented into their method and device (Figures 6-9) and one of ordinary skill in the art would recognize that the incorporation of the calibration zones of Robinson et al into the method and device of Dafforn et al would also require the application of the corresponding reagents for the calibrant in the calibration zones. Robinson also

specifically teaches a releasable reagent predeposited. Further, Robinson et al clearly disclose (page 5, lines 7-15) that the device can be a test strip (same as Dafforn) and Robinson clearly states the advantages of using calibration zones and calibration reagents (page 3, lines 15-16 and page 14, lines 24-26) in a test device and method.

Appellant argues that claims 17 and 31 are nonobvious over Dafforn et al and Self. Appellant argues that the deficiencies of Dafforn et al are not resolved by Self. That is, while Self discloses an immunoassay using an amplified cyclic detection system, Applicants find no teaching or suggestion by Self relating to a method or device for determination of an analyte in a sample and a flow matrix employing a combination of biospecific affinity reactants and liquid application zones and flow as defined in claims 1 and 18. This is not found persuasive Examiner has not relied upon Self for these limitations but rather has relied upon Dafforn et al for these limitations. Further, Dafforn et al specifically teach that the device may be utilized in any number of assay wherein absorbent material is utilized to assist the flow of liquid away from a contact portion where the absorbent material is contacted with a medium containing the analyte to be determined or reagents for analyzing for the analyte (col 4, lines 11-16). Further, Dafforn et al disclose that the device can be used to detect autoimmune antibodies and antibodies to allergens (col 5, lines 1-6). Since, Self et al disclose that immunoassays are used for the detection and/or determination of autoimmune disease. It is the Examiner's position that it would have been obvious to one of ordinary skill in the art to combine the teachings of Dafforn et al and Self et al.

Appellant argues that claims 34 and 35 are nonobvious over Dafforn et al and Goerlach-Graw et al. Appellant argues that Dafforn et al fails to teach zone spacers comprising a strip attached to the flow matrix. This is not found persuasive because Examiner has not relied upon Dafforn et al for teaching a strip attached to the flow matrix but rather has relied upon Goerlach-Graw et al for this teaching. Appellant argues that Goerlach-Graw et al does not resolve the deficiencies of Dafforn et al. Appellant argues that Goerlach-Graw et al fails to teach a single flow matrix having liquid application zones in series therein, as required in claims 1 and 18. This in not found persuasive because Examiner has not relied upon Goerlach-Graw et al for teaching a single flow matrix having liquid application zones in series therein, as required in claims 1 and 18, but rather has relied upon Dafforn et al for these teachings. Appellant argues that such a strip is contrary to promoting contact between developer and conjugate as desired by Dafforn et al. This is not found persuasive because the instantly recited claims do not exclude contact between the liquids and further it appears that Appellant is relying upon the previous arguments that Dafforn et al teaches mixing of the developer and the complex. This is not found persuasive because as stated above Dafforn et al does not teach mixing of the developer and the complex. Further, Goerlach-Graw specifically teaches the advantages of incorporating such strips into a flow matrix.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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